

Patented TamperStop Technology



PATENTS:

Two recently granted US Patents and the filings of foreign patents stipulate the design... and application of various versions Rfid devices placed directly on top of the caps. One of the most unique options is a dual layer cap which contains a Tuned Frequency Rfid chip and antenna. If any attempts are made to remove or pierce the cap to remove the contents or to add a contaminant, the Rfid chip goes dead. A simple and inexpensive interrogation device can immediately identify tampered medications or counterfeit vials of medications with a counterfeit cap.

For more information or questions, please contact:

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Tamperstop.net Shutting the Door on Counterfeit Drugs

Nothing is absolutely impossible to counterfeit given enough time and money, and staying ahead of counterfeiters is an ongoing process. Protecting your product, so that is no longer profitable to counterfeit, is the goal, and TamperStop technology provides the simple and inexpensive solution which virtually eliminates counterfeiting.



TamperStop 13mm Vial Caps Pull Tab and Open Top 2 US and Foreign Patents

Introduction

Tamperstop draws on its 23 years of high-tech experience in over 32 different Chinese, Asian, Russian, Indian and South American Countries to develop anti-counterfeiting solutions for pharmaceutical products. For generations, the aforementioned have survived by counterfeiting all forms of goods and technologies, driving Tamperstop to create a Reverse-Intuitive approach to product design.

Instead of working from a functional and customer aesthetics standpoint, they looked at products

and asked themselves, "how could we break into any sealed vial or package and remove, replace, or duplicate the contents".

Tamperstop then designed a bullet-proof cap with a wide array of optional, reverse-compatible security layers, and patented pedigree features including Rfid, Holograms, Embedded Digital Encryption, and Non-Reversible Thermo Chromic Phase-Shifting Thermal Indicating Solutions. These high-tech options, plus molded-in 1D through 3D bar codes, provide a full range of proven reliable technology to defeat all attempts against your product.



TamperStop 13mm Vial Caps Pull Tab and Open Top US Patent # 11,643,476

Current Aluminum Cap Liabilities

Tamperstop identified the liabilities associated with aluminum crimp seals which have been an industry staple for almost 100 years. First introduced as a thin lead foil (Pb) it is only in the past 50 or so

years that Aluminum replaced the lead foil as an alternative material.

For less than \$200 on eBay, you can buy a complete hand vial crimping tool for 13mm and 20mm, with extra seals and company embossing logos. This gives literally any person the ability to open and re-seal any 13mm or 20mm vial. Regardless of sophisticated anti-counterfeit features on the label, the ability to covertly gain entrance and re-seal a vial of any product, opens the specter of tampering, adulteration, dilution, and even terrorism.

Handling and loading aluminum caps during processing generates aluminum oxide (Al_2O_3)

preventing the filled vials from being permanently and securely sealed in a clean room atmosphere to an assured pedigree. This means that users of aluminum caps have to take the filled vials off-site to be sealed, thus compromising the true pedigree of the contents.

Industry studies have suggested that the process of high speed crimping of the aluminum cap can drive Al_2O_3 particulate matter under the diaphragm rubber seal and into the medical solution. Also, the structure and presence of aluminum as a cap material distorts the electronic signal strength preventing the physical placement of Rfid technology on the top of the vial where it can be best read by the scanners. Future use of Rfid in medical packaging will be absolutely

essential for the creation of a much needed industry wide pedigree assurance program.

Tamperstop caps are injection molded, using a patented process, from an FDA approved polymer. The components are first injection molded too small to fit the vials and are then crosslinked (a process used to bond the molecular chains together) heated, and then mold expanded a second time using a proprietary and patented process.

During this second thermal expansion process, the parts are heated approximately 200 degrees F above their original melting point (properly crosslinked polymers cannot melt and will decompose at temperatures in excess of their previous melting point). This second expansion takes the caps to a significantly greater dimension that is specifically calculated to be within 1% of their maximum percent elongation. During this expansion



Cap with Center Hologram



Irreversible Thermo-chromic Tamper Indicators

process, the caps can have a multitude of additional progressive security features incorporated to meet the customer's needs.

In the cap's crosslinked and heated state (to the materials glass transition temperature T_g), it is possible to include a wide variety of

interchangeable mold inserts. These mold inserts make it possible to include; corporate logos, simple date codes, 1D-3D embossed bar codes, non-reoccurring alpha-numeric ID's, and even 3D digitally encrypted



Laser Excited Digital Hologram Diffraction
Patent Pending

holograms.

Also, at this second molding stage, an extremely important security feature is added to the cap known as the Tactile Sensor. Tactile Sensors are small protrusions on the surface of the cap which can easily be felt through surgical gloves without damaging them

Normally, Tactile Sensors cannot be consistently injection molded into a counterfeit cap due to the flow characteristics of the molten, non-crosslinked polymer. However, after crosslinking, Tamperstop's polymer has far greater strength and flow integrity which allows the sensors to be pulled into a shaped cavity in the tooling and thinned out to a fraction of a millimeter.

When manufacturing is completed, the caps fit easily onto the vial and can be installed onsite, and in-line, during manufacturing with only a slight modification to most existing automated capping

TAMPERSTOP



equipment. Once the cap is snapped over the vial lip, the cap permanently locks onto the vial and resists all attempts at non-destructive removal.

The cap now acts like a giant spring, due to the memory of the cap's first molded shape and size that was imparted into the polymer during the crosslinking process, that cannot be pried off without obviously damaging the cap.

Repeated thermal cycling at high and low temperatures (-40 to +290 Deg F) causes the cap to grip the vial with even greater force. During the second



Tamper and Counterfeit-Indicating Rfid Insert with 500K Encrypted Pedigree Storage Memory

thermal mold expansion, the polymer was literally stretched, like a huge rubber band that has been pulled to 99% of its ultimate percent elongation, or stated another way, to within less than 1% of its maximum percent elongation. When tampered with, the cap's only option is to retract back, with enormous force bringing any polymer creep to bear against the seal area of

Digital Memory Storage Hologram which has been embossed into the molded part after the crosslinking process during the molding process.

FEATURES:

- Tamperstop Closures perform properly in cyclic conditions of (-40 to +290 deg F).
- All autoclave, sterilizations temperatures are well within the thermal performance limits.
- All products meet EPC Global/EPCIS Pedigree mandates, and are made of 100% FDA approved polymers.
- Optional features include the ability to have standard or pull-tab openings with Parental or child friendly pull strengths for child self injection.
- Vivid or machine readable-only Holograms in 2D or 3D, and some with digital encryption and information storage as optional features.
- Non-reversible Thermo Chromic heat sensors can be added for pre-shipment sterilization verification or for environmental shipping condition monitoring.
- Products are also available in virtually any color matching Pantone color charts. (Some lighter colors do slightly increase production cycle time due to their IR reflective nature).
- After a small initial tooling expense, raised logos, company symbols, and even Braille can be added at no additional expense in production volumes.
- All 13mm and 20mm caps are compatible with in-line capping, sealing, sterilization, and cryogenically treated medication packaging.
- On Rfid modules, virtually any Rfid chip can be adapted, or the standard Atmel Crypto RF and Phillips Chips can be used suitable for Military applications with full encryption requirements -64 bit Mutual Authentication Protocol- random number generator with keys.
- Tamperstop crosslinked and re-expanded technology has been independently tested and verified as suitable and compatible for this application.



the cap. Thus making the seal strength even stronger, to the point where the polymer fractures if stretched too far. The caps actually can be removed with heat, however, immediately as the caps leave the vial, they shrink and revert to their much smaller originally molded size and cannot be re-expanded.

Another great advantage of crosslinked polymers is that after crosslinking, the polymers, formulations and mechanical expansions cannot be accurately analyzed or identified, nor can the exact level of crosslinking be determined by possible counterfeiters. The final Tg (Glass Transition Temperature) of the polymers used in the construction of the Tamperstop cap exceeds 305 deg F allowing for all forms of autoclaving. After the cap is fully molded, additional, even more sophisticated pedigree security features that can be added.

Background

Just enter “Counterfeit Drugs” into any computer Search Engine and you will immediately find hundreds of reports, TV excerpts, newspaper articles, and technical reports from highly respected organizations, such as The World Health Organization, (WHO) describing the growing global crisis of counterfeit medication throughout the world. To date, there have been multiple products and technologies introduced into the marketplace that all focus on protecting the Label and exterior of the packaging (the proverbial sides and windows of the barn), while totally ignoring the vial opening, cap, and closure (the barn door) which has been left wide open to allow counterfeiters, terrorists, to remove the contents of valid medications and replace them at will with cheap imitations, fake, adulterated and even purposefully contaminated chemicals or biological agents.

It has only been by our greatest fortune that no terrorist has yet to place a bacterial agent in just a few of these counterfeit medications that would spread unspeakable diseases and economic collapse across any country in a matter of days. Additionally, Counterfeiters have newer and better printing equipment than many of

our leading Pharmaceutical companies, and recent arrests have clearly proven that foreign governments have paid their people to enter our country and work for high technology companies with the specific intent to steal technology and packaging artwork. Why is this happening? So that sponsoring governments can introduce fake copies of real medications before the companies can legally introduce them to the marketplace. To date State governments have not only released these individuals in exchange for them admitting to their Foreign Government sponsorship, but they have even granted them the privilege of staying in the US as protected US citizens. Until our Federal Government takes over the prosecution of these individuals from the States, we are on our own to protect ourselves with our own technology and to absolutely self-police the release the licensing and sale of this technology to only recognized legitimate Pharmaceutical companies.

Cost

Starting with basic molded, crosslinked and expanded caps; the production cost (in volumes) is comparative to, or less than existing aluminum crimp-on caps. Tamperstop caps allow for the total capping and labeling operation to be moved back into the pharmaceutical company’s own clean room facility. The price of this cap, in comparison to all the benefits, is almost non-measurable.

Tampering and Counterfeits of our Products

The question arises why a counterfeiter simply cannot injection mold a look-alike plastic part with none of the features or technology. The simplest answer is that the elastic characteristics of standard non-crosslinked polymers do not allow for the high level of polymer strength and stretch required to place the molded parts on a vial and have them be tight enough not to easily be turned or rotated by hand. Additionally, counterfeit caps would not have the tactile sensors, which is a standard security feature on all cap configurations. Finally, the technology of building an injection mold in such small diameters of 13mm to 20mm without using a retractable core took 3



Digital Memory Storage Hologram which has been embossed into the molded part after the crosslinking process.

years of developments and multiple failures by the most notable mold makers in Germany and Japan.

Most counterfeiters simply scan and print a copy of your label and place it on a vial of water. The Tamperstop technology virtually provides an almost limitless variety of resins colors that can be matched to Pantone color charts to identify not only your company, but also the medications, the process, facility, etc.

The Cost of Not Considering Tamperstop:

Lost revenues to the Pharmaceutical companies this year have been estimated to exceed \$32-\$50 Billion Dollars. This is roughly 1/3 of what President Obama has stated is needed for a comprehensive health insurance program to protect 100% of all Americans.

There is also an estimated additional \$7-\$12 Billion Dollars lost each year, caused by medical errors, and resulting recall programs.

The Human Death toll:

Conservative estimates from several sources equate the human death toll directly related to counterfeit medications at 200,000 each for the US, Canada, and 300,000 for the EU, 600,000 for China, and a staggering 700,000 for Africa just from “fake tuberculosis and malaria drugs”. This is equivalent to (10) ten fully loaded jumbo jets crashing every day.

The exact toll may be significantly higher since many people were already sick and the medications they were given had absolutely no active ingredients or were actually toxic themselves.

The Past Solutions:

Today, most attempts at preventing counterfeiting have centered around the label areas of the packaging, with Holograms, Tracers, Taggants, ThermoChromic, UV, and Infrared Excited Inks, along with several highly encrypted, digitally embedded, non-repetitive numbering systems as well as 2D and 3D Bar code variations. Not near as simplistic as during the 1982 Tylenol terrorist episode, and next time, simple heat-sealed lids, and protective shrink-wraps are not going to keep the counterfeiters and terrorists out of our medications. As recently as 2 years ago, there was great hope that RFID's would be introduced into all packaging with a nation-wide collective database to provide a real-time verification of product pedigree from cradle to grave through Federal and State mandates.

Unfortunately, when the dates arrived, no suitable tested system had yet to be put into practice. In addition there were problems with the sensitivity of RFIDs that prevented them from being placed on the top surface of medical packaging with aluminum caps due to communication interference. A few

About the Author

Lawrence G. Martinelli:

President Tamperstop Security Technology Inc. Larry holds a B.S. in Chemistry and Biology from St. Mary's College in Moraga, California as well as post graduate degrees in Engineering and Polymer Chemistry from Stanford and NYU. As an entrepreneur and inventor, Larry holds over 20 patents and is well respected across many industries.

Previously, Larry worked for Kaiser Research and Chemicals, Raychem, Memorex, and Verbatim before starting Heritage Corporation and Consultech Engineering in 1983. Heritage and Consultech have jointly installed over 100 Turn-Key manufacturing plants in 32 countries including a wide variety of technology transfers from magnetic-media plants to industrial fruit dehydration plants around the world.

Larry's greatest enjoyment comes from the real-world applications of polymer materials development and international business joint ventures. Larry has devoted himself to working exclusively to the Anti-Counterfeit and Anti-Tamper Projects since 2004.



major US and Japanese companies even tried to develop plastic co-polymers that would stand up to high autoclave temperatures while allowing the RFIDs to perform properly.

Fortunately, these issues have been remedied with Tamperstop's line of patented security and RFID protection systems that can be utilized with other patented technologies to stop the global crisis of counterfeit medications.

A Final Thought

Imagine being a CEO reading the morning paper about a competitor's product involvement in a Smallpox terrorist attack. Then further down the article you are quoted describing the safety of your company's product, because you selected Tamperstop to secure your reputation and the final patient's health.

Reference and Support Sources

There is an outstanding, clear, and concise Tutorial Technical Review of the entire Pharmaceutical Counterfeiting Methods, proposed solutions in detail, and the cost in human lives written and documented by a Mr. Anil Deisingh of the University of the West Indies: http://www.keionline.org/miscdocs/deisingh_pharmaceutical_counterfeiting.pdf

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Features

Tamperstop Patented Security Technology Features

High temperature FDA approved Intelligent-Polymers

High temperature FDA approved Intelligent-Polymers that maintain shape and seal integrity at temperatures that far exceed all autoclave and shipping conditions

Multi-Latch Intelligent-Polymer closures

Multi-Latch Intelligent-Polymer closures that replace contaminating aluminum vial crimps.

Cap inside of cap designs

Cap inside of cap designs; assure product integrity by requiring that the outside cap (containing the protective RFID) be twisted off thus destroying the RFID antenna before the vial contents can be accessed.

Molded-in Encrypted Digital Holograms

Molded-in Encrypted Digital Holograms that are placed in the caps at the time they are injection molded, they cannot be read or duplicated by counterfeiting agents but can store and be machine read at 1 MB/sq mm

Temperature Indicating Polymers

Temperature Indicating Polymers, and Ink Jet printable Non-Reversible Thermo-Chromic inks, that indicate tamper attempts when the most common tamper technique of hot-air guns is used.

Phase-Changing Intelligent-Polymers

Phase-Changing Intelligent-Polymers that change state from a liquid to a solid, if tampering is attempted. This feature, when combined with the non-reversible thermochromic inks provide a highly visible tamper indicator that changes color from a white to dark magenta within seconds of a tamper attempt.

Counterfeiting deterrents

Counterfeiting deterrents; company and product Logo's or codes that can be pressure-embossed into the sides of the cap and will disappear with the addition of thermal tampering well above autoclave temperatures

Standard FCM Fractal Dual-Molded

Standard FCM Fractal Dual-Molded, Snap-On, but non-removable polymer caps, lids and closures. (Pull-Tab-Remove versions of the product are available in 13mm and 20mm vial sizes)

Patented RFID permanently crosslinked embedded modules

Patented RFID permanently crosslinked embedded modules with non-repeating individualized serial numbers tailored to each manufacturer.

Patented and specifically custom tailored Real-Time Software

Patented and specifically custom tailored Real-Time Software, that tracks, records, and constantly assures the unique lifetime perigee of the product

Patented Binary Optically Encrypted Elements

Patented Binary Optically Encrypted Elements (images) that can be EDM'd into customer's Molds (added from our master) produce visual or non-visible, (but machine readable) information molded into polymer product components. These images can be read by the human eye or scanner, but they cannot be copied or duplicated into a counterfeit molded part.

Other options

Other options include raised company logos, choice of custom colors, Braille and even non reversible Thermochromic (Temperature sensing) and magnetically encoded Ink-Jet™ applied date codes

Binary Optically Encrypted (BOE) enabled options and Smart SensorVials™ the counterfeit and tampering of pharmaceutical products is prevented.

All TamperStop products are made from FDA approved polymers, fully compatible and Integratable into clean room environments.

Existing capping production lines and sealing equipment accept TamperStop Snap-On closures with minimum retrofit.

All TamperStop products are protected from counterfeiting or illegal duplication by our proprietary Fractal Dual-Molding Process, which produces parts with dramatically increased melting points and pre-stressed polymer chains that assure life-long consistent packaging seal strength. Multiple autoclaving have no effect upon the product closures.
